A PROPOSAL TO
THE SOUTH CAROLINA COMMISSION ON HIGHER EDUCATION
TO ESTABLISH AT CLEMSON UNIVERSITY THE

CENTER FOR BIOLOGICAL INTERFACES OF ENGINEERING (CBIOE)

Submitted By

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November 2006

I. CLASSIFICATION

This proposal requests South Carolina Commission on Higher Education Center (CHE) designation for the Clemson University *Center for Biological Interfaces of Engineering* (CBIOE).

As a research unit at Clemson University, CBIOE has been in existence for one (1) year. The proposed Center is **NEW** in terms of CHE designation. The date of designation of CBIOE as a CHE approved Center will precede the proposed date of implementation: August 1, 2007.

CIP code: not applicable

II. JUSTIFICATION

IIa. Purpose/Objective: The CBIOE mission is four fold: (1) to disseminate cutting edge engineered tissue technologies internationally, thus building the reputation of the existing multidisciplinary programs, (2) to develop an internationally recognized "go to" engineered tissue technology toolbox, available through CBIOE online seminars, short courses, industrial workshops, and databases, (3) to maximize economic development for the State of South Carolina through the establishment of an internationally recognized Engineering Research Center, and (4) to establish a model recruitment and professional development program that facilitates the access of economically disadvantaged South Carolina students to higher education. CBIOE is structured to capitalize on and unify the already existing expertise in unique and cutting edge tissue engineering and biomaterials technologies as well as Clemson University (CU) strengths in communication and application based teaching technologies.

Unique aspects of CBIOE will include:

- Establishment of an engineering center with educational location at a medical center
- Incorporation of preclinical animal expertise and infrastructure
- Development of translational models leveraging veterinary products
- Designation of enabling technologies as crucial research thrust areas
- Tangible involvement of clinical/surgical/veterinary collaborators
- Establishment of a student recruitment/retention program with regional and economic focus

IIb. National and State-level Need: Tissue engineering is the creation of biologically based solutions to health problems, using tools such as molecular biology, proteomics, stem cell technologies, and tissue engineering to repair the human machine. Upon scrutiny of biotechnology industries it is noted that there is a clear disparity between the high tech regenerative research that is conducted at universities and the technology that industry is willing to immediately invest in. It has further been observed, that in the biotechnology industry, there is a lack of "testbeds" (or device evaluation services) and this is a major reason for slow technology transfer from the academic setting to the marketplace. For example, industry is leery of large scale, high-risk ventures such as development of a total heart. Currently, two National Science Foundation (NSF) sponsored tissue engineering centers exist, one largely focused on cellular mechanisms and use of stem cells, and the second focused on surface modification of implant materials. Both Centers have self-admitted gaps in technology transfer from bench top to bedside and, although both are in close proximity to major medical centers, both have minimal to no clinical input. CBIOE is thus positioned to span the gap between basic scientific research using the well-established Clemson University-Medical Center and Veterinary College partnerships and through the continued commitment to multidisciplinary research. The role of CBIOE in these ventures may include the testing and standardizing of low risk regenerative medicine devices to deliver to industrial collaborators. By becoming a niche provider

of these services, the aim is to facilitate interactions between local industry and the institutions. By concurrently pursuing high-risk research in the academic setting, the Center will position itself to lead the tissue engineering device market and provide a continuing line of evolving devices.

CBIOE, as an application-based learning center, will provide an attractive learning site for many South Carolina students, particularly those underrepresented (by race, gender, or economics) in the Science, Technology, Engineering, and Mathematics disciplines. Student demand for involvement in CBIOE projects is high, while the current acceptance rate is limited. Students trained in CBIOE will acquire communication and technical skills by working in a multi-disciplinary environment that will afford them employment opportunities in a variety of disciplines. To date, CBIOE graduates have been gainfully employed as product managers in the biomedical device industry, as researchers in the regulatory industry, and as Chief Executive Officers in small biomedical start-up companies.

IIc.1 Relationship of Proposed Program to Existing Programs at Clemson University

As an inter-disciplinary research unit of the College of Engineering and Science at Clemson University that spans across Colleges, CBIOE already integrates faculty and student researchers across many departments and programs. CBIOE also has strong ties to Clemson's *Center for Advanced Engineering Fibers and Films*, the *Spiro Center for Entrepreneurial Leadership*, and the *Programs for Educational Enrichment & Retention*. The Center will include faculty from the Departments of Bioengineering, Animal and Veterinary Sciences, Biological Sciences, Chemical Engineering, Chemistry, Communication Studies, English, Management, Materials Science and Engineering, Mechanical Engineering, Physics, Plastic and Reconstructive Surgery, Vascular Surgery at Clemson University, the Medical University of South Carolina (MUSC), and the Greenville Hospital System (GHS). The newly approved Regenerative Medicine Chairs at MUSC, the University of South Carolina (USC), and Clemson University will each have membership in the Center.

The proposed plan dictates four thrusts with two emphasis areas unifying the thrusts. Individually, the thrusts will provide cutting edge research; combined together, the thrusts will form the backbone for current as well as future medical devices. The thrusts are: Minimally Invasive Surgical Technologies (CU ECE, GHS, CU Physics, CU-MUSC Bioengineering), Rapid Prototyping (CU-ECE, CU-MUSC Bioengineering, CU Mechanical Engineering), Histological and Surgical Analyses (CU-MUSC Bioengineering, CU Animal and Veterinary Sciences, CU Biological Sciences, GHS), and Advanced Biomaterials (CU Chemistry, CU Chemical Engineering, CU-MUSC Bioengineering, CU Materials Science and Engineering). The four thrust areas will be spanned by emphasis areas in Communications and in Bioinformatics, spearheaded by the Departments of Communication Studies and English at Clemson University and the Department of Genetics & Biochemistry at Clemson University, respectively.

IIc.2. Relationship of Proposed Program to Other Institutions

CBIOE investigators are developing collaborative arrangements with the AO Foundation (Switzerland), Greenville Hospital System, MUSC, UNC-C, UNC-CH, Harvard University, Walter Reed, Tufts, Nanyang Technical University, and Singapore University. The relevant collaborators are actively writing proposals for joint funding and are developing inter-institutional research, educational, and technology transfer programs. CBIOE investigators are in the process of building educational alliances with the Howard Hughes Medical Institute, the AO Foundation, and TriCounty Technical College.

IId. Centrality to Clemson University Mission:

Clemson University (CU) is uniquely poised to provide a model innovation structure that will focus the technologies and people necessary to maintain a leadership role in biomaterials. Research in CBIOE will contribute to the containment and reduction of health care costs and will improve the cost effectiveness, quality, and accessibility of the health care system. Nationally, research funding opportunities for biomedical and bioengineering translational research have exceeded $100M. CBIOE will provide the needed infrastructure and environment for securing competitive funding. Strategically located, this program will further position South Carolina to become a leader in biomedical and bioengineering research and technology development by providing the required intellectual and clinical environment sought by the medical device industry. According to U.S. Census Bureau projections, the growth rate of the population over 65 years-of-age will increase in the coming decades: by 2050, the number of Americans older than 65 will more than double, and the number living beyond age 85 will increase four-fold. It is predicted that this population will require a wide variety of implantable devices to palliate tissue/organ aging and failure. Supported by this aging population and new products, the U.S. medical-device market represents 44% of the world medical-device market, with a total market capitalization of $57.6B in 2002. The cardiovascular medical device market alone is the largest medical-device sector, at an estimated $17B in annual worldwide sales, followed by the orthopaedic medical device market. According to the Centers for Medicare & Medicaid Services, health care expenditures rose 9.6% in 2001 and are expected to continue rising at an annual rate of 6.9% for the next 10 years. These trends suggest a sizeable and growing market for the biotechnology and medical device industry. CBIOE will enable the development of clinically relevant medical technology and the transfer of this technology from the laboratory to bedside. Indeed, the base of successful economic development consists of high-level, globally competitive research conducted by a diverse team of investigators.

CBIOE will thus address the needs of the state by meeting the CHE guidelines of:

- Creating a well-educated citizenry,
- Raising the standard of living of South Carolinians,
- Improving the quality of life,
- Meeting changing work force needs,
- Creating economic development opportunities,
- Positioning the state to be competitive in a global economy, and
- Fashioning a new generation of public sector and private sector leaders.

IIe. Similarities/Differences with Those Programs at Other Institutions

Clemson University Bioengineering, with which CBIOE is affiliated, is the oldest Bioengineering graduate degree granting program in the state and is one of the pioneering programs in the nation, the focus of which is on the development of biomedical devices, including tissue engineered devices. The Department of Bioengineering is strategically positioned to facilitate the rapid development of CBIOE, as it boasts a well organized network of university, local, and state wide collaborators including scientists, engineers, clinicians, businesspersons, and communication experts. There are no other bioengineering departments or engineered tissue technology programs of this kind in the state.

III. ENROLLMENT

Since CBIOE will not serve as a degree-granting academic unit, there are no admissions criteria or target enrollment figures. For this reason, the Projected Total Enrollment and Estimated New Enrollment tables have been omitted from this proposal. The students conducting research on

sponsored programs that support CBIOE will be enrolled in degree-granting academic units at Clemson University (or at partner institutions through exchange programs, for example). The academic departments in which the CBIOE affiliated faculty reside will be responsible for the administration of the student's programs and degree requirements. Research funds generated by Center faculty will provide for both thesis and non-thesis support (i.e., stipends, hourly salaries, etc.) for the students, including undergraduates.

IV. CURRICULUM

CBIOE will neither offer courses nor administer a degree-granting program. Affiliated faculty will maintain their curriculum related duties within their home academic departments.

Table I.

List Staff by Rank (e.g. Professor #1, Professor #2, Associate Professor #1, etc)	Highest Degree Earned	Field of Study	Teaching in Field (Yes/No)
Endowed Chair & Professor #1	PhD	Bioengineering	Yes
Endowed Chair & Professor #2	PhD	Animal & Veterinary Sci.	Yes
Professor #1	PhD	Business/Entrepreneurship	Yes
Associate Professor #1	PhD	Bioengineering	Yes
Associate Professor #2	PhD	Animal & Veterinary Sci.	Yes
Assistant Professor #1	PhD	Electrical & Computer Eng.	Yes
Assistant Professor #2	PhD	Electrical & Computer Eng.	Yes

V. FACULTY

Initially, CBIOE faculty will be constituted of those 7 faculty, listed in Table I, who will submit grant applications through the Center. All participating faculty will hold primary appointments in existing academic units and will be considered *Senior Fellows* of the Center. A faculty member with the title of Senior Fellow must fund Center projects through a sponsored research grant or contract to participate in the research program of the Center. Two new tenure-track faculty will be added to CBIOE in Year 1 and Year 2; two new research faculty will be added in Years 3 and 4, and one research faculty will be added in Year 5. New faculty will be strategically added to support the CBIOE mission. At present, Dr. Karen Burg of the Department of Bioengineering will continue to serve as Director. The faculty holding sponsored research programs through the Center at the time of any personnel change will recommend a new Director to the Deans representing Colleges with affiliated CBIOE faculty and Vice President for Research for approval.

The initial appointment of the Director will be at most for one-half FTE on a calendar year basis, where one Full-Time Equivalent is defined by Clemson University as 12 credit hours. Funds for the release time and summer salary of the Director and associated faculty will be derived either from the home academic department or through overhead that is returned on grant or contract research generated by the Center's faculty. Table I above details the rank and academic qualifications of each faculty member who will be involved in CBIOE (either presently or anticipated in the near future). Table II, shown below, substantiates expected Center support for personnel.

Table II.

UNIT ADMINISTRATION/FACULTY/STAFF SUPPORT						
YEAR	**NEW**		**EXISTING**		**TOTAL**	
	Headcount	FTE	Headcount	FTE	Headcount	FTE
Administration						
2007 – 08	0	0	1	0.5	1	0.5
2008 – 09	0	0	1	0.5	1	0.55
2009 – 10	1	0.75	1	0.75	2	0.50
2010 – 11	0	0	2	0.75	2	0.50
2011 – 12	0	0	2	0.75	2	0.50
Faculty						
2007 – 08	2	0	7	0	9	0
2008 – 09	1	0	9	0	10	0
2009 – 10	2	0	10	0	12	0
2010 – 11	2	0	12	0	14	0
2011 – 12	2	0	14	0	16	0
Staff						
2007 – 08	2	2	0	0	2	2
2008 – 09	1	1	2	0	3	3
2009 – 10	1	1	3	0.25	4	4
2010 – 11	2	0.0	3	0.75	4	4
2011 – 12	0	0	5	1.25	4	4

VI. PHYSICAL PLANT

Space for CBIOE's personnel and infrastructure (including equipment purchased under sponsored programs) will be housed in either space allocated to the individual faculty member by their respective academic departments, in multi-investigator space allocated, or in space currently allocated to CBIOE on the Greenville Memorial Hospital main campus.

VII. EQUIPMENT

Center supported equipment will be available to nonparticipating faculty, departments, and organizations for a fee, set at the University level, that reflects the costs of operation, maintenance, and upgrade. Major equipment required for this initiative includes tissue culture, histological, and rapid prototyping equipment.

VIII. LIBRARY RESOURCES

The library resources already existing on campus will be sufficient for the operation of the Center and its projects.

IX. ACCREDITATION, APPROVAL, LICENSURE, OR CERTIFICATION

Not applicable. However, CBIOE will be evaluated through several existing procedures:

(1) the individual affiliated faculty are evaluated yearly through Clemson's Faculty Activity System (FAS) by their respective Departmental Chairs and Deans. In addition, untenured faculty undergo yearly review and reappointment and tenured faculty undergo periodic post-tenure review to ensure continued productivity and alignment with Departmental, College, and university missions and goals.
(2) CBIOE, as a research organization, is evaluated through sponsored research reviews by the respective granting agency.
(3) Further metrics used to gauge the productivity of CBIOE include: **scholarship** (publications, presentations, grants, students supported and graduated funded through Center projects), **peer-recognition** (national/international awards, invited lectures/presentations, organizational involvement in conferences/workshops, professional society leadership roles), **technology transfer** (patents, licenses, and start-up companies), and enrollment of industrialists and clinicians in CBIOE organized workshops and symposia.

X. ESTIMATED COST

CBIOE research will be self sustaining through research grants, contract research services, and indirect funds generated on sponsored programs. As noted above, substantial funding has been realized and is expected to continue at the greater than $3,000,000 per year mark with expansion expected as the new faculty are hired.

Clemson University will request $1,000,000 reoccurring "below-the-line" State funding in FY07 to develop synergistic programs to complement CBIOE's pending National Science Foundation (NSF) Partnerships for Innovation, NSF PIRE and pending Department of Defense and Keck Foundation proposals. By way of example, the funding would support:

Educational Programs: Recruitment and professional development of regional underserved candidates, with focus on underrepresented groups of economic need, through the newly established CBIOE *Call Me Doctor* scholarship and professional development program. Students teaching biomedical concepts to SC middle school teachers with priority to under-represented counties in SC, summer research projects for under-represented high school students.

Entrepreneurial Resource Development: Educational workshops to entrepreneurs & networking events, forums in support of knowledge economy initiatives, forums promoting biomedical cluster initiatives, seed and Angel investing workshops highlighting investment opportunities in engineered tissue technologies, strategy for attracting biomedicine-related companies to the region, campaigns for biomedicine-related business development.

Table III

ESTIMATED COSTS BY YEAR						
CATEGORY	**1st 2004-2005**	**2nd 2005-2006**	**3rd 2006-2007**	**4th 2007-2008**	**5th 2008-2009**	**TOTALS**
Program Administration	76,200	76,200	114,300	114,300	114,300	495,300
Faculty Salaries	0	0	127,000	200,054	213,554	540,608
Graduate Assistants	181,800	202,000	242,400	282,800	323,200	1,232,200
Clerical/Support Personnel	117,300	178,300	255,300	255,300	255,300	1,061,500
Supplies and Materials	50,000	60,000	70,000	70,000	70,000	320,000
Library Resources	0	0	0	0	0	0
Equipment	1,000,000	500,000	100,000	100,000	100,000	1,800,000
Facilities	150,000	150,000	150,000	150,000	150,000	750,000
Other (Identify)	0	0	0	0	0	0
TOTALS	1,575,300	1,166,500	1,059,000	1,172,454	1,226,354	6,199,608
SOURCES OF FINANCING BY YEAR						
Estimated FTE Revenue Generated from the State	0	0	0	0	0	0
Tuition Funding (New students only)	0	0	0	0	0	0
Other State Funding (Legislative Appropriations)	1,000,000	1,000,000	1,000,000	1,000,000	1,000,000	5,000,000
Reallocation of Existing Funds	0	0	0	0	0	0
Federal Funding	3,000,000	3,000,000	3,000,000	3,000,000	3,000,000	15,000,000
Other Funding*	5,000,000	0	0	250,000	250,000	5,500,000
TOTALS	9,000,000	4,000,000	4,000,000	4,250,000	4,250,000	25,500,000

Note that listed amounts for salaries and stipends include fringe.

* The establishment of an endowment for CBIOE's *Call Me Doctor* scholarship program is a present priority of Clemson University's Office of Advancement.

XI. ADMINISTRATIVE STRUCTURE

The Center will process all fiscal operations through the standard Departmental channels under the direction of the Center Director or grant principal investigators. Prospective Senior Fellows will indicate their desire to conduct projects through the Center by written application or sponsored research proposal to the Director.

An advisory group that will set and monitor general policy for the Center will include the Deans of Colleges with affiliated faculty (or a designee at the Dean's discretion), the *Senior Fellows*, the Center Director, and a select group of industrial/clinical personnel representing the sponsoring agencies.

Institutional Approval	**Date Approved**
Thomas Keinath *Dean, College of Engineering and Science*	May, 2004
Academic Council	August, 2004
Administrative Council	September, 2004
Doris R. Helms *Provost*	September, 2004
James F. Barker *President*	September, 2004
Clemson University Board of Trustees	October 22, 2004